Fees in Respect of Medical Devices Regulations

SOR/98-432

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FINANCIAL ADMINISTRATION ACT

Fees in Respect of Medical Devices Regulations

P.C. 1998-1509 26 August, 1998

His Excellency the Governor General in Council, on the recommendation of the Minister of Health and the Treasury Board, pursuant to paragraphs 19(1)(*a*)[a] and 19.1(*a*)[a] of the *Financial Administration Act* and, considering that it is in the public interest to remit certain debts, pursuant to subsection 23(2.1)[b] of that Act, hereby makes the annexed *Fees in Respect of Medical Devices Regulations*.

[a] S.C. 1991, c. 24, s. 6[b] S.C. 1991, c. 24, s. 7(2)

FEES IN RESPECT OF MEDICAL DEVICES REGULATIONS

INTERPRETATION

Definitions

1. (1) The definitions in this subsection apply in these Regulations.

"actual gross revenue" « *recettes brutes réelles* »

"actual gross revenue" means the amount billed by a manufacturer during the period referred to in paragraph 8(2)(*a*) or (*b*), as the case may be, for sales in Canada of a medical device. (*recettes brutes réelles*)

"annual gross revenue" « *recettes brutes annuelles* »

"annual gross revenue" means

(*a*) in sections 12 and 13, the amount billed by a manufacturer during a fiscal year for sales in Canada of a medical device for which the manufacturer holds a medical device licence; and

(*b*) in sections 15 to 15.3, 16.1 and 16.2, the amount billed by an establishment during a fiscal year for sales in Canada of medical devices.

"anticipated gross revenue" « *recettes brutes anticipées* »

"anticipated gross revenue" means the amount that a manufacturer expects to bill during the period referred to in paragraph 8(2)(*a*) or (*b*), as the case may be, for sales in Canada of the medical device for which a reduction in the licence fee is sought. (*recettes brutes anticipées*)

"Minister" « *ministre* »

"Minister" means the Minister of Health. (*ministre*)

Other words and expressions

(2) Unless the context otherwise requires, words and expressions used in these Regulations have the meaning assigned to them by the *Medical Devices Regulations*. SOR/2000-312, s. 1.

PART 1
MEDICAL DEVICE LICENCE FEES

Application

Applicable classes

2. This Part applies to medical devices that are subject to the *Medical Devices Regulations*, other than the provisions of Parts 2 and 3 of those Regulations, and that are classified into one of Classes II to IV under sections 6 and 7 of those Regulations.

Class II Medical Device Licence

Fee -- Class II medical device

3. (1) The fee to be paid for the examination of a Class II medical device licence application made under section 32 of the *Medical Devices Regulations* is $200 and is payable by the manufacturer at the time that the application is submitted.

Reinstatement of a Class II medical device licence

(2) For the purposes of this Part, every provision in these Regulations that applies to an application for a Class II medical device licence made under section 32 of the *Medical Devices Regulations* also applies to a request for the reinstatement of such a licence made under subsection 41(2) of those Regulations.

Class III or IV Medical Device Licence

Fee -- Class III or IV medical device

4. (1) Subject to subsection (2), the fee to be paid by a manufacturer for the screening and the examination of a Class III or IV medical device licence application made under section 32 of the *Medical Devices Regulations* is the sum of $200 plus

(*a*) in the case of a Class III medical device licence, for each component set out in column 1 of an item of Schedule 1 that relates to the application, the fee set out in column 2 of that item; or

(*b*) in the case of a Class IV medical device licence, for each component set out in column 1 of an item of Schedule 2 that relates to the application, the fee set out in column 2 of that item.

Fee -- sale authorized to a qualified investigator

(2) If a manufacturer has received authorization under subsection 83(1) of the *Medical Devices Regulations* to sell a medical device to a qualified investigator, the fee to be paid by the manufacturer for the screening and the examination of an application made under section 32 of those Regulations for a licence in respect of that medical device is the sum of $200 plus

(*a*) in the case of a Class III medical device licence, for each component set out in column 1 of items 2 to 4 of Schedule 1 that is related to the application, the fee set out in column 2 of that item; or

(*b*) in the case of a Class IV medical device licence, for each component set out in column 1 of items 3 to 11 of Schedule 2 that is related to the application, the fee set out in column 2 of that item.

Reinstatement of a Class III or IV medical device licence

(3) For the purposes of this Part, every provision in these Regulations that applies to an application for a Class III or IV medical device licence made under section 32 of the *Medical Devices Regulations* also applies to a request for the reinstatement of such a licence made under subsection 41(2) of those Regulations.

Class III or IV Medical Device Licence Amendment

Fee -- amendment to medical device licence

5. The fee to be paid by a manufacturer for the screening and the examination of a medical device licence amendment application made under paragraph 34(*a*) or (*b*) of the *Medical Devices Regulations* is

(*a*) in the case of a Class III medical device licence, the amount obtained by adding, for each component set out in column 1 of an item of Schedule 1 that is related to the application for amendment, the fee set out in column 2 of that item; or

(*b*) in the case of a Class IV medical device licence, the amount obtained by adding, for each component set out in column 1 of an item of Schedule 2 that is related to the application for amendment, the fee set out in column 2 of that item.

Screening Only

Fee -- screening only

6. Despite sections 4 and 5 and paragraph 9(1)(*b*), if a manufacturer receives a notice from the Minister stating that its application for a Class III or IV medical device licence or for a medical device licence amendment has been screened but has not been accepted for examination, the fee payable by the manufacturer on receipt of the notice from the Minister is

(*a*) 10 per cent of the fee referred to in section 4 or 5, as the case may be; or

(*b*) if the Minister grants a reduction in the fee under subsection 8(2), 10 per cent of the fee referred to in paragraph 9(1)(*b*).

Schedule for Payment of Fees

Payment schedule

7. If the fee to be paid under section 4 or 5, paragraph 9(1)(*b*) or subsection 10(1) is

(*a*) $5,000 or less, the fee is payable at the time that the application is submitted; or

(*b*) more than $5,000, the fee is payable as follows, namely,

(i) 10 per cent on receipt of a notice from the Minister stating that the application has been screened,

(ii) 65 per cent on receipt of a notice from the Minister stating that the application has been accepted for examination, and

(iii) 25 per cent on receipt of a notice from the Minister stating that the examination of the application has been completed.

Reduction of Fees

Application for a reduction

8. (1) A manufacturer may apply to the Minister for a reduction in the fees to be paid under subsection 3(1) or section 4 or 5 when the manufacturer submits an application for

(*a*) a medical device licence under section 32 of the *Medical Devices Regulations*; or

(*b*) a medical device licence amendment under paragraph 34(*a*) or (*b*) of those Regulations.

Mandatory reduction in fee

(2) The Minister must grant a reduction where the Minister has reasonable grounds to believe that the fee payable under subsection 3(1) or section 4 or 5 will be more than 5 per cent of the manufacturer's anticipated gross revenue from the medical device to which the application relates during

(*a*) in the case of an application for a medical device licence under section 32 of the *Medical Devices Regulations*, the two-year period beginning on the date that the medical device is first offered for sale in Canada or is subsequently re-offered after the reinstatement of a licence; and

(*b*) in the case of an application for a medical device licence amendment under paragraph 34(*a*) or (*b*) of those Regulations, the two-year period beginning on the date of issuance of the amended licence.

Amount of Reduced Fees

Fee and payment schedule

9. (1) When, under subsection 8(2), the Minister grants a reduction in the fee payable for an application for a medical device licence or for a medical device licence amendment, the reduced fee payable by the manufacturer is

(*a*) for the examination of an application for a Class II medical device licence, $50, payable on submission of an application for the reduction in the fee; or

(*b*) for the screening and the examination of an application for a Class III or IV medical device licence or a medical device licence amendment, an amount equal to 5 per cent of the manufacturer's anticipated gross revenue from the medical device during the period referred to in paragraph 8(2)(*a*) or (*b*), as the case may be, payable in accordance with section 7.

Statement -- Class II medical device

(2) In the case of a Class II medical device for which a reduction in fee was granted under subsection 8(2), the manufacturer shall, on expiry of the period referred to in paragraph 8(2)(*a*) or (*b*), as the case may be, provide the Minister with a statement, certified as true

and correct by the person responsible for the manufacturer's financial affairs, of the manufacturer's actual gross revenue in that period from that device.

Sales records -- Class III or IV medical device

(3) In the case of a Class III and IV medical device for which a reduction in fee was granted under subsection 8(2), the manufacturer shall, on expiry of the period referred to in paragraph 8(2)(*a*) or (*b*), as the case may be, provide the Minister with sales records prepared in accordance with generally accepted accounting principles and certified as true and correct by the person responsible for the manufacturer's financial affairs.

Revocation of Reduction in Fees

Revocation

10. (1) Despite section 8, if the actual gross revenue billed by a manufacturer for a medical device during the period referred to in paragraph 8(2)(*a*) or (*b*), as the case may be, is more than the anticipated gross revenue declared by the manufacturer for that device in its application under subsection 8(1) for a reduction, the reduction in the fee is revoked and the fee payable is the lesser of

(*a*) the full fee under subsection 3(1) or section 4 or 5, as the case may be, and

(*b*) 5 per cent of the manufacturer's actual gross revenue from the medical device during the period referred to in paragraph 8(2)(*a*) or (*b*), as the case may be.

Payment schedule

(2) Where the full fee becomes payable under subsection (1), the difference between the amount already paid and the full fee shall be payable on the expiry of the 60 days following the period referred to in paragraph 8(2)(*a*) or (*b*), as the case may be.

Remission of Overpayment

Minister must remit overpayment

11. The Minister must remit to a manufacturer an amount equal to the difference between the amount paid and the fee payable under subsection 3(1) or section 4, 5 or 6, as the case may be, if the amount paid to the Minister by the manufacturer

(*a*) under section 4 or 5, as the case may be, is greater than the screening fee payable under section 6; or

(*b*) under paragraph 9(1)(*b*) on the basis of the anticipated gross revenue is greater than an amount equal to 5 per cent of the manufacturer's actual gross revenue from the device during the period referred to in paragraph 8(2)(*a*) or (*b*), as the case may be.

Fee for the Right to Sell a Licensed Class II, III or IV Medical Device

Fee

12. (1) Subject to subsection (2), where a manufacturer holds a Class II, III or IV medical device licence under section 26 of the *Medical Devices Regulations* on November 1 of any year and, during the manufacturer's previous fiscal year, has an annual gross revenue from that medical device in an amount set out in column 1 of an item of the table to this subsection, the manufacturer must pay, on November 1 of the year, the fee for the right to sell that licensed medical device set out in column 2 of that item.

TABLE
FEE BASED ON ANNUAL GROSS REVENUE

Item	Column 1 Annual gross revenue from the medical device	Column 2 Fee to be paid for the right to sell medical device
1.	Less than $20,000	$ 50
2.	$20,000 or more	$100

Statement of annual gross revenue

(2) The fee set out in column 2 of item 1 of the table to subsection (1) must be accompanied by a statement, certified as true and correct by the person responsible for the manufacturer's financial affairs, declaring that the annual gross revenue for the applicable medical device was less than $20,000.

Reduction

(3) Despite subsection (1) and subject to subsection (4), if the total amount of the fees to be paid under subsection (1) by a manufacturer for all of the manufacturer's licensed medical devices is greater than an amount equal to 1.5 per cent of the total annual gross revenue from all of the manufacturer's licensed medical devices, the total amount of the fee under that subsection for all of those medical devices shall be reduced to an amount equal to that 1.5 per cent.

Statement of total annual gross revenue

(4) The reduced fees set out in subsection (3) must be accompanied by a statement, certified as true and correct by the person responsible for the manufacturer's financial affairs, that sets out the total annual gross revenue of the manufacturer from all of its licensed medical devices.

Verification of Actual Gross Revenue and Annual Gross Revenue

Audited sales records

13. (1) If the Minister determines, on the basis of any information available to the Minister, that the statements provided in accordance with subsection 9(2) or 12(2) or (4) or the sales records provided in accordance with subsection 9(3) are not adequate to determine the manufacturer's actual gross revenue or annual gross revenue, the Minister may require the manufacturer to submit sales records that have been audited by a qualified independent auditor and those records shall be used for the purpose of determining the fee payable.

Full fee payable on failure to submit required documents

(2) If, on expiry of the 60 days following the period referred to in paragraph 8(2)(*a*) or (*b*), as the case may be, a manufacturer fails to submit to the Minister the statements referred to in subsection 9(2), the sales records referred to in subsection 9(3) or the audited sales records referred to in subsection (1), the difference between the amount already paid and the full fee is immediately payable.

Correct fee payable on verification

(3) If the audit referred to in subsection (1) determines that the amount paid was incorrect, the difference between the amount paid and the correct amount is immediately payable to, or shall be reimbursed by, the Minister, as the case may be.

PART 2
ESTABLISHMENT LICENCES

Application

Applicable classes

14. This Part applies to establishments that import or sell medical devices that are subject to the *Medical Devices Regulations*, other than the provisions of Parts 2 and 3 of those Regulations, and that are classified into one of Classes I to IV under sections 6 and 7 of those Regulations.

Fee -- Establishment with Revenue in a Previous Fiscal Year

Amount

15. (1) The fee to be paid by an establishment for the issuance of an establishment licence under section 46 of the *Medical Devices Regulations* or for the reinstatement of an establishment licence under section 51 of those Regulations is, if, as of the date the establishment submits its application for the issuance or request for the reinstatement of the licence, the establishment has completed at least one fiscal year in which it had annual gross revenue,

(*a*) $2,120; or

(*b*) an amount equal to 1 per cent of the establishment's annual gross revenue for its previous fiscal year, if that amount is less than the amount set out in paragraph (*a*) and the establishment submits the statement referred to in subsection (3).

When payable

(2) The fee is payable on the day on which the licence is issued or reinstated.

Statement of revenue

(3) If the amount set out in paragraph (1)(*a*) is greater than an amount equal to 1 per cent of an establishment's annual gross revenue for its previous fiscal year, the establishment may submit with its application for the issuance or request for the reinstatement of an establishment licence a statement, certified as true and correct by the person responsible for the establishment's financial affairs, that sets out the establishment's annual gross revenue for its previous fiscal year. SOR/2000-312, s. 2.

Fee -- Establishment without Revenue in a Previous Fiscal Year

Fee

15.1 (1) Subject to section 15.2, if, as of the date an establishment submits an application for the issuance or request for the reinstatement of an establishment licence referred to in subsection 15(1), the establishment has not completed at least one fiscal year in which it had annual gross revenue, the fee to be paid by the establishment for the issuance or reinstatement of the licence is $2,120.

When payable

(2) The fee is payable on the day on which the licence is issued or reinstated. SOR/2000-312, s. 2.

Reduced Fee and Remission

Application for fee reduction

15.2 (1) If, as of the date an establishment referred to in subsection 15.1(1) submits an application for the issuance or request for the reinstatement of an establishment licence, the establishment expects that the fee specified in that subsection will be greater than an amount equal to 1 per cent of the establishment's annual gross revenue for its first fiscal year in which it will have annual gross revenue, the establishment may submit to the Minister an application for a fee reduction together with its application for the issuance or request for the reinstatement of the licence.

Initial statement

(2) The establishment shall submit with the application for a fee reduction a statement, certified as true and correct by the person responsible for the establishment's financial affairs, that

(*a*) indicates that, as of the date the application is submitted, the establishment has not completed at least one fiscal year in which it had annual gross revenue;

(*b*) sets out the date the establishment began or will begin to sell medical devices in Canada; and

(*c*) sets out the date of the end of the establishment's first fiscal year in which it will have annual gross revenue.

Statement of revenue

(3) Within 90 days after the end of the establishment's first fiscal year in which it has annual gross revenue, the establishment shall submit to the Minister a statement, certified as true and correct by the person responsible for the establishment's financial affairs, that sets out the establishment's annual gross revenue for that fiscal year.

Reduced fee and remission

(4) If the amount paid by the establishment for the issuance or reinstatement of the licence is greater than an amount equal to 1 per cent of the establishment's annual gross revenue for its first fiscal year in which it has annual gross revenue and the statement referred to in subsection (3) has been submitted within the time specified in that subsection, the fee is reduced to that latter amount and remission is hereby granted of an amount equal to the difference between those amounts, which amount the Minister shall refund to the establishment. SOR/2000-312, s. 2.

Verification of Annual Gross Revenue

Audited sales records

15.3 (1) If the Minister determines, on the basis of any information available to the Minister, that a statement submitted under subsection 15(3), 15.2(3), 16.1(2) or 16.2(3) is not adequate to determine an establishment's annual gross revenue, the Minister may require the establishment to submit sales records that have been audited by a qualified independent auditor and those records shall be used for the purpose of determining the fee payable or the amount of remission.

Full fee payable

(2) If, on the expiry of 60 days after the Minister requires an establishment to submit audited sales records, the establishment fails to submit those records to the Minister, the difference between the fee specified in paragraph 15(1)(*a*) or subsection 15.1(1), as applicable, and the net amount paid is immediately payable.

Correct fee payable on verification

(3) If the audit referred to in subsection (1) determines that the net amount paid is less than the amount that should have been paid, the difference between those amounts is immediately payable.

Remission

(4) If the audit referred to in subsection (1) determines that the amount that should have been paid is less than the net amount paid, remission is hereby granted of an amount equal to the difference between those amounts, which amount the Minister shall refund to the establishment.

Definition

(5) In this section, "net amount paid" means the amount that has been paid by the establishment in respect of the application or request to which the statement referred to in subsection (1) relates, less any amount that has been refunded to the establishment under subsection 15.2(4), 16.1(3) or 16.2(4). SOR/2000-312, s. 2.

PART 3
TRANSITIONAL PROVISIONS AND COMING INTO FORCE

Transitional Provisions

Applications received between July 1, 1998 and August 31, 1998

16. (1) This section applies to an application for a Class II, III or IV medical device licence made under section 32 of the *Medical Devices Regulations* or a Class III or IV medical device licence amendment made under paragraph 34(*a*) or (*b*) of those Regulations that is submitted during the period from July 1, 1998 to August 31, 1998.

Fee

(2) The fee to be paid by a manufacturer

(*a*) for the examination of an application for a Class II medical device licence referred to in subsection (1) is, if on September 1, 1998 that examination has not commenced, the fee set out in subsection 3(1) or paragraph 9(1)(*a*), as the case may be;

(*b*) for the screening and the examination of an application of a Class III or IV medical device licence or medical device licence amendment referred to in subsection (1) is, if on September 1, 1998

(i) the screening of the application has not commenced, the fee set out in section 4, 5 or 6 or paragraph 9(1)(*b*), as the case may be,

(ii) the screening of the application has commenced, 90 per cent of the fee set out in section 4 or 5 or paragraph 9(1)(*b*), as the case may be, or

(iii) the examination of the application has commenced, no fee.

Payment schedule

(3) The fee referred to in

(*a*) paragraph (2)(*a*) and subparagraph (2)(*b*)(i) is payable

(i) where the fee is $5,000 or less, on receipt of a notice from the Minister that the following had not commenced before September 1, 1998:

(A) the examination of the application for a Class II medical device licence, or

(B) the screening of the application for a Class III or IV medical device licence or medical device licence amendment; or

(ii) where the fee is more than $5,000, in accordance with subsection 7(*b*); and

(*b*) subparagraph (2)(*b*)(ii) is payable as follows, namely,

(i) 25 per cent on receipt of a notice from the Minister that the application has been accepted for examination, and

(ii) 75 per cent on receipt of a notice from the Minister that the examination of the application is completed.

Previous fiscal year

16.1 (1) This section applies to an establishment that

(*a*) before the day on which this section comes into force, submitted an application for the issuance or request for the reinstatement of an establishment licence referred to in subsection 15(1) in respect of the year 2000; and

(*b*) as of the date it submitted the application or request referred to in paragraph (*a*), had completed at least one fiscal year in which it had annual gross revenue.

Application for fee reduction

(2) If the amount paid by the establishment in respect of the application or request referred to in subsection (1) is greater than an amount equal to 1 per cent of the establishment's annual gross revenue for its previous fiscal year, the establishment may submit an application for a fee reduction together with the statement referred to in subsection 15(3) no later than 60 days after the day on which this section comes into force.

Reduced fee and remission

(3) If the amount paid by the establishment in respect of the application or request referred to in subsection (1) is greater than an amount equal to 1 per cent of the establishment's annual gross revenue for its previous fiscal year and the statement referred to in subsection 15(3) has been submitted within the time specified in subsection (2), the fee is reduced to that latter amount and remission is hereby granted of an amount equal to the difference between those amounts, which amount the Minister shall refund to the establishment. SOR/2000-312, s. 3.

No previous fiscal year

16.2 (1) This section applies to an establishment that

(*a*) before the day on which this section comes into force, submitted an application for the issuance or request for the reinstatement of an establishment licence referred to in subsection 15(1) in respect of the year 2000; and

(*b*) as of the date it submitted the application or request referred to in paragraph (*a*), had not completed at least one fiscal year in which it had annual gross revenue.

Remission

(2) If the establishment paid a fee of $2,530 in respect of an application for the issuance of an establishment licence referred to in subsection (1), remission is hereby granted to the establishment of an amount equal to $410, which amount the Minister shall refund to the establishment.

Application for fee reduction

(3) If the establishment expects that the amount paid by the establishment in respect of the application or request referred to in subsection (1), less any amount refundable to the establishment under subsection (2), will be greater than an amount equal to 1 per cent of the establishment's annual gross revenue for its first fiscal year in which it has annual gross revenue, the establishment may submit an application for a fee reduction together with the statement referred to in subsection 15.2(2) no later than 60 days after the day on

which this section comes into force, if it submits the statement referred to in subsection 15.2(3) within 90 days after the end of that fiscal year.

Reduced fee and remission

(4) If the amount paid by the establishment in respect of the application or request referred to in subsection (1), less any amount refundable to the establishment under subsection (2), is greater than an amount equal to 1 per cent of the establishment's annual gross revenue for its first fiscal year in which it has annual gross revenue and the statement referred to in subsection 15.2(3) has been submitted within 90 days after the end of that fiscal year, the fee is reduced to that latter amount and remission is hereby granted of an amount equal to the difference between those amounts, which amount the Minister shall refund to the establishment. SOR/2000-312, s. 3.

Coming into Force

Service fees

17. (1) Subject to subsections (2) and (3), these Regulations come into force on September 1, 1998.

Fees for right to sell

(2) Section 12 comes into force on November 1, 1999.

Fees for establishment licences

(3) Part 2 comes into force on January 1, 2000.

SCHEDULE 1
(Sections 4 and 5)
CLASS III MEDICAL DEVICES

	Column 1	Column 2
Item	Component of the application	Fee ($)
1.	Description of the medical device and the materials used in its manufacture and packaging, its features that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented and a summary of reported problems with the medical device in countries other than Canada in which the device has been sold	140
2.	Summary and conclusions of studies on which the manufacturer relies to ensure that the medical device meets the safety and effectiveness requirements of the *Medical Devices Regulations*	1,470

3.	A copy of the medical device label	170
4.	In the case of a near patient *in vitro* diagnostic device, a summary of the investigational testing conducted on the device using human subjects representative of intended users and under conditions similar to the conditions of use of the device	440

SCHEDULE 2
(Sections 4 and 5)
CLASS IV MEDICAL DEVICES

	Column 1	Column 2
Item	Component of the application	Fee ($)
1.	Description of the medical device and the materials used in its manufacture and packaging, its features that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented and a summary of reported problems with the medical device in countries other than Canada in which the device has been sold	140
2.	Risk assessment and risk reduction measures in respect of the medical device adopted to satisfy the safety and effectiveness requirements of the *Medical Devices Regulations*	1,000
3.	Specifications of the materials used in the manufacture and packaging of the medical device	680
4.	Manufacturing process of the medical device	1,360
5.	In the case of an *in vitro* diagnostic device, the studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements of the *Medical Devices Regulations*:	
	(*a*) pre-clinical studies	2,090
	(*b*) clinical studies	3,880
6.	In the case of a medical device other than an *in vitro* diagnostic device, the studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements of the *Medical Devices Regulations*:	
	(*a*) pre-clinical studies	3,270
	(*b*) clinical studies	4,400
7.	Process validation studies on which the manufacturer relies to ensure that the medical device meets the safety and effectiveness requirements of the *Medical Devices Regulations*	850
8.	Software validation studies on which the manufacturer relies to ensure that the medical device meets the safety and effectiveness requirements of the *Medical Devices Regulations*	2,020
9.	A copy of the medical device label	170

10.	In the case of a medical device, other than an *in vitro* diagnostic device, manufactured from or incorporating animal or human tissue or their derivatives, objective evidence of the biological safety of the medical device	2,620
11.	In the case of a near patient *in vitro* diagnostic device, detailed information on investigational testing conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use of the device	2,410